

APPENDIX A

Data Sources and Methods

In an effort to comprehensively address the task of recommending accreditation standards for Human Research Review Programs (HRRPs), the committee reviewed and considered various data sources in a concerted effort to cast a broad net for the collection and assessment of information. These sources included presentations before the committee from interested organizations, individuals, and federal agencies as well as formal public comments; a review of relevant literature; and commissioned draft standards for accreditation. A summary description of the committee's evidence-gathering methods follows.

PRESENTATIONS AND PUBLIC COMMENT

Over the course of the study, the committee requested and received written responses and presentations from organizations and individuals representing many perspectives of accreditation and human subjects protections in general. The committee felt it was important to receive as much input as possible from public and private groups involved with or seeking involvement in the accreditation process and human subjects protections, as well as from health professional and other organizations. To accomplish this, the committee convened a public meeting on December 18, 2000 and a larger public forum on January 22, 2001 to gather information and hear from groups and individuals. The speakers at these meetings are listed in Box A-1.

BOX A-1 Organizations and Individuals Appearing Before the Committee**December 18, 2000**

Sanford Chodosh, Public Responsibility in Medicine and Research
 Michael Hamm, Michael Hamm and Associates
 David Korn, Association of American Medical Colleges
 Greg Koski, HHS Office for Human Research Protections
 Charles McCarthy, Kennedy Institute of Ethics
 Richard Rettig, RAND Corporation
 Marjorie Speers, National Bioethics Advisory Commission
 Mark Yessian, HHS Office of Inspector General

January 22, 2001

Jessica Briefer French, National Committee for Quality Assurance
 Jim Burris, Department of Veteran Affairs
 Marie M. Cassidy, Citizens for Responsible Care and Research
 Steve Erickson, Boston College
 William L. Freeman, Indian Health Service
 Edward F. Gabriele, Naval Medical Research Center
 Peter Goldschmidt, Medical Care Management Corporation
 Vera Hassner Sharav, Citizens for Responsible Care and Research
 John Isidor, Shulman and Associates IRB, Inc.
 Jonathan Knight, American Association of University Professors
 David Lepay, Food and Drug Administration
 Felice Levine, American Sociological Association/ Consortium of Social
 Science Associations
 John R. Livengood, Centers for Disease Control and Prevention
 Barbara J. LoDico, University of Medicine and Dentistry of New Jersey
 Dan Masys, University of California, San Diego
 Cherlyn Mathias, Private Citizen
 Nick Reuter, Substance Abuse and Mental Health Services Administration
 Philip Rubin, National Science Foundation
 John Smith, Morehouse School of Medicine
 David P. Stevens, Association of American Medical Colleges
 Irene Stiith-Coleman, Department of Health and Human Services
 Margaret VanAmringe, Joint Commission on Accreditation of Health
 Organizations
 Myrl Weinberg, National Health Council

February 21, 2001

Greg Koski, HHS Office for Human Research Protections
 Belinda Seto, NIH Office of Extramural Research

During the first committee meeting, a number of speakers addressed the history of human subjects protections; the industrialization of clinical research; and provided overviews of the HHS Office of Inspector General activities, the HHS Office of Human Research Protections (OHRP), and accreditation processes; among other topics.

At the second meeting, the committee convened a public forum in order to hear a variety of perspectives on the preliminary draft accreditation standards formulated by Public Responsibility in Medicine and Research (PRIM&R), the accreditation process, and the protection of human research subjects. Over 125 people attended the meeting. Representatives of government and regulatory organizations, private accrediting groups, associations, institutions, IRBs, social science groups, research participants, and investigators made short presentations that were subject to comment and questioning from the committee and audience.

In order to include as many people and groups as possible, the committee sent out a mailing that included an announcement of the public forum, a one-page description of the study, the committee roster, and a cover letter explaining the committee's purpose for requesting the information. The letter was sent to a variety of interested people and groups via fax, email, and listservs, and asked those interested to send or fax comments pertinent to the committee's task and to respond to the PRIM&R draft standards for accreditation. The committee also used the project website [www.iom.edu/hrrp] to elicit comments on the project and the draft standards by providing project details, contacts, and links to pertinent information. The materials submitted to the committee supplemented those obtained by the committee through the literature review and public meetings.

A small portion of the third committee meeting was held in open session to hear additional comments from project sponsors.

In addition to the participants listed in Box A-1, many other individuals attended and participated in the public meetings, and/or provided written information to the committee. All registered participants for the January 2001 forum are listed below:

Aronson, Debra	Brown, Rachel
Ashe, Warren K.	Association of Independent
Howard University School of	Research Institutes
Medicine	
Bailey, Veronica	Bruinooge, Suanna S.
Children's Hospital,	American Society of Clinical
Washington, D.C. IRB	Oncology
Berger, Douglas	Burkom, Diane
National Bioethics Advisory	Battelle Centers for Public Health
Commission	Research and Evaluation
Brooks, Tricia	Byerly, Wesley G.
Capitol Associates, Inc.	Wake Forest University School of
	Medicine

Caia, Matt
Committee on National Statistics,
National Academy of Sciences

Cantor, Michael
Veterans Health Administration
National Center for Ethics

Carley, John M.
U.S. Environmental Protection
Agency

Carpentier, Richard
National Council on Ethics in
Human Research

Chesley, Francis D., Jr.
Agency for Healthcare Research
and Quality

Chodosh, Sanford
Public Responsibility in
Medicine and Research

Cohen, Jeffrey
Office for Human Research
Protections

Coleman, Laura
Eli Lilly and Co.

Cuccherini, Brenda A.
Veterans Health Administration

Daly, Nancy
American Society of Therapeutic
Radiology and Oncology

DeCrappeo, Anthony
Council on Governmental
Relations

DeRenzo, Evan G
Washington Hospital Center

Dessaint, Danelle
Division of Behavioral and Social
Sciences and Education, NAS

deWolf, Virginia A.
NRC Committee on National
Statistics

Dinsdale, Henry
National Council on Ethics in
Human Research

Dong, Bertha
U.S. General Accounting Office

Dunn, Cindy M.
University of Rochester

Dustira, Alicia K.
Office of Research Integrity

Eaglen, Robert
Liaison Committee on Medical
Education

Eckenwiler, Lisa A.
Old Dominion University

Erickson, Stephen
Boston College

Feldman, Laura S.
National Association of Children's
Hospitals

Fish, Bob
U.S. Army Medical Research and
Materiel Command

Fleming, Yolanda A.
National Medical Association

Foote, Donna
Newsweek Magazine

Furtek, Edward
University of California, San Diego

Gallegos, Alice
SUNY Stony Brook

Gasparis, George
Office of Human Research
Protections

Gelb, Romy
U.S. General Accounting Office

Gemski, Liz
Capitol Associates

Goebel, Paul W., Jr.
Office of Human Research
Protections

Gordon, Daniel M.
Walter Reed Army Institute of
Research

Gordon, Valery M.
Office of Extramural Programs,
OER, OD, NIH

Gottfried, Kate
Office for Human Research Pro-
tections

Graziano, Alfred S. Jr.
U.S. Air Force

Gross, Lauren G.
American Association of
Immunologists

Hamm, Michael
Michael Hamm and
Associates/PRIM&R

Han, Sang
National Association of State
Universities and Land-Grant
Colleges

Harpel, Richard
National Association of State
Universities and Land-Grant
Colleges

Hartnett, Terry
Clinical Trials Advisor

Hauck, Robert J. P.
American Political Science
Association

Higgins, Yvonne K.
U.S. Air Force

Hurt, Valerie

Kalf, George F.
Thomas Jefferson University

Kaneshiro, Julie
Office of Science Policy, NIH

Kester, Kent E.
Walter Reed Institute of Research

Khin-Maung-Gyi, Felix
Chesapeake Research Review, Inc.

Kohn, Adam M.
Shaw Pittman

Kuehl, Patricia
PAREXEL International

Kulakowski, Elliott C.
Society of Research Administrators
International/
Albert Einstein Healthcare
Network

Lechter, Karen
Food and Drug Administration

Lee, Bonnie M.
Food and Drug Administration

Levine, Jen
Washington Drug Letter
Linde-Serge, Marian
Food and Drug Administration

Lorden, Joan F. Ph. D.
University of Alabama at
Birmingham

Macko, Gail
Tactical Research, LLC

McFarland, Jeff
Society of Research Administrators
International

Meyer, Roger E.
Association of American Medical
Colleges

Milstein, Alan
Sherman, Silverstein, Kohl, Rose &
Podolsky

Mitchell, Marcus
Glaxo-SmithKline

Mitchell, Mary H.
Harvard University

Morgan, Charlene
Department of Navy, Bureau of
Medicine and Surgery

Nightingale, Stuart
Department of Health and Human
Services

Noble, Gary R.
Johnson&Johnson

Noble, John H., Jr.
Catholic University of America
Okie, Susan
Washington Post

Overbey, Mary Margaret
American Anthropological
Association

Panicker, Sangeeta
American Psychological
Association

Papagni, Paul
Columbia University/New York
Presbyterian Medical Center

Patel, Nilam
Agency for Healthcare Research
and Quality

Patterson, Wayne
The University of Texas Medical
Branch at Galveston

Paulsen, Cindy University of Chicago	Schwartz, Harvey A. Agency for Healthcare Research and Quality
Perricord, Douglas Quintiles Transnational	Seto, Belinda National Institutes of Health
Polmar, Suzanne K. Yale University	Shamoo, Adil E. University of Maryland School of Medicine
Pospisil, George C. National Institute of Neurological Disorders and Stroke, NIH	Sharpe, Angela Consortium of Social Science Associations
Powell, James H. National Medical Association	Shawver, Mary N. Diamond Healthcare Corporation
Puglisi, Tom PricewaterhouseCoopers	Sherwin, Joseph R. University of Pennsylvania
Radcliffe, Sara PhRMA	Siang, Sanyin American Association for the Advancement of Science
Reid, Ken <i>Bioresearch Monitoring Report</i>	Silver, Howard J. Consortium of Social Science Associations
Russel-Einhorn, Michele PricewaterhouseCoopers	Simonson, Kristin American Society of Therapeutic Radiology and Oncology
Sanford, Sandra NCQA	Skedvold, Paula National Institutes of Health Office of Behavioral and Social Sciences Research
Scanley, Anne National Institute of Allergy and Infectious Diseases	Skelton, Margaret Ann School of Medicine and Health Sciences, George Washington University
Scharke, Cliff Office for Human Research Protections	
Schrode, Kristi Bennet, Turner & Coleman, LLP	

Smedberg, Paul
National Health Council

Spilker, Bert
PhRMA

Stith-Coleman, Irene
Department of Health and Human
Services

Straf, Miron L.
Directorate for Social, Behavioral,
and Economic Sciences,
National Science Foundation

Studer, Evelyn
Research Triangle Institute

Swanson, Dennis
University of Pittsburgh
Institutional Review Board

Turman, Richard J.
Association of American
Universities

Vincent, Angela
National Medical Association

Waterman, Paula
Department of Veterans Affairs,
Office of Research Compliance
and Assurance

Weiner, Susan L.
The Children's Cause, Inc.

Wenner, Karen A.
McKesson HBOC Pharmaceutical
Partners Group

Wichman, Alison
NIH Office of Human Subjects
Research

Wingard, Jennifer
National Association of State Uni-
versities and Land Grant Colleges

Zarin, Deborah
Agency for Healthcare Research
and Quality

Zimmerman, Janet F.
IMPACT Consulting Group

The following people and organizations submitted written comments to the committee about accreditation programs and/or the PRIM&R Standards:

American Political Science
Association

Association of American Universi-
ties/Council on Governmental
Relations/ National Association
of State Universities and Land
Grant Colleges

Citizens for Responsible
Care & Research

Cornblath, David R.
Johns Hopkins Medicine

Eckenwiler, Lisa A.
Old Dominion University

Erickson, Stephen
Boston College

Feussner, John R.
Department of Veterans Affairs,
Veterans Health Administration

Freeman, William
Indian Health Service

Gabriele, Edward F.
Naval Medical Research Center

Kulakowski, Elliott C.
Society of Research Administrators
International

Levine, Felice J.
American Sociological Association/
Consortium of Social
Science Associations

National Medical Association
Oakes, David A.
Stanford University

Overbey, Mary Margaret
American Anthropological
Association

Patterson, Wayne
The University of Texas Medical
Branch at Galveston
Richards, R. Henry
American Academy of
Pharmaceutical Physicians
Rubin, Phillip
National Science Foundation

Ryan, Stephen J.
University of Southern California

Swanson, Dennis
University of Pittsburgh

Shopes, Linda
Pennsylvania Historical & Museum
Commission

Townsend, Ardis Noreen
Private Citizen

Vasgird, Daniel R.
Research Foundation of the City
University of New York

Weinberg, Myrl
National Health Council

All written materials presented to the committee were reviewed and considered with respect to the task. This material can be examined by the public. The public access files are maintained by the National Research Council Library at 2001 Wisconsin Avenue, N.W., Harris Building, Room HA 152, Washington, DC 20007; tel: (202) 334-3543.

LITERATURE REVIEW

In order to be thorough in their review, the committee conducted multiple literature searches and read numerous articles, book chapters, and reports concerning the protection of human subjects of research and its components during the course of the study. The materials provided addressed topics including the history of human subjects protections; the laws, processes, and groups that regulate human research; critiques of the current system for protecting human

research subjects; sample accreditation programs; and ethical issues surrounding human research.

DRAFT STANDARDS FOR ACCREDITATION

Due to the fast-track nature of this study, the Institute of Medicine sought to assist the committee in completing its task in a timely manner. For this reason, the IOM funded the completion of a two-year effort by PRIM&R to establish accreditation standards. The resulting standards were intended to assist the committee in its deliberations about accreditation strategies and their strengths and weaknesses.

In addition, in the course of the committee's analysis, the draft standards developed by NCQA under contract with the Department of Veterans Affairs were provided to the committee for inclusion in their assessment of accreditation standards.